

The Community Immunization Registries Manual Chapter on Confidentiality

Summary

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In 1998, an Initiative on Immunization Registries was undertaken by the National Vaccine Advisory Committee (NVAC), with support from the Centers for Disease Control and Prevention (CDC) and the National Vaccine Program Offices (NVPO). The protection of privacy and confidentiality was identified as critical to the successful development of State- and community-based immunization registries. During the Initiative, over 100 experts provided testimony at four public meetings, and 21 parent focus groups were held. In January 1999, NVAC approved a report entitled "Development of Community- and State-Based Immunization Registries". In this report, NVAC recommended the development of minimum specifications to protect privacy and confidentiality in immunization registries.

A CDC-led Privacy and Confidentiality Implementation Team with representatives from the All Kids Count Program, NVPO and state health departments developed minimum specifications for the protection of the privacy of registry participants and the confidentiality of data contained in registries. NVAC provided extensive input and the document was reviewed by leading privacy experts and other interested stakeholders. The specifications and the guidelines for their implementation in a manner that is consistent with the values of the community are contained in an updated chapter on confidentiality. The specifications are consistent with Secretary Shalala's recommendations to Congress for privacy legislation and with the proposed privacy regulations. NVAC approved the updated chapter in February 2000.

The confidentiality policies in the chapter are based on the following guiding principles.

- An immunization registry is a tool for monitoring and improving population-based health as well as the personal health of individuals. The information contained in the registry provides immunization decision support. Registries do not replace parental or provider responsibility.
- The protection of privacy and the maintenance of confidentiality are essential to the successful development of immunization registries.
- Confidentiality policies are designed to balance the clinical and public health need for information and the privacy rights of the individual.

- Confidentiality policies are based on the principles of fair information practice, including the individual's right to know what information about him or her is in a record and how it is used, and to request amendments or corrections to the record.
- The decision whether or not to participate in the registry and the decision whether or not to vaccinate are separate and distinct decisions.
- All immunization registries, including registries that are part of integrated information systems, must ensure that privacy is protected.

The minimum specifications include, but are not limited to, the following:

- **Confidentiality Policies**
All immunization registries must have a written confidentiality policy that is consistent with applicable laws and applies to everyone who has access to the registry.
- **Agreements to Protect Confidentiality**
All authorized immunization registry users must sign an agreement indicating that they understand the terms of the confidentiality policy, including the penalties for violations, and they agree to comply with it. An employer can sign the agreement indicating that he or she is responsible for the actions of his or her staff.
- **Notification**
Patients and/or their parents or legal guardians must be notified about the existence of the registry, what information will be contained in it, what the information will be used for, with whom the information will be shared, procedures for review and correction of information, and how to exercise choice about participation.
- **Choice**
Parents must be able to choose whether or not to participate in the registry and to change the decision at any time. Parents and children must not be penalized for choosing not to participate. Personally identifiable information of those who have chosen not to participate must not be shared.
- **Use of Immunization Registry Information**
Each registry must identify the purposes for which it is collecting immunization

information, and inform all authorized user and parents or guardians. Information in the registry must only be used for the purposes for which it was collected.

- **Access to and Disclosure of Immunization registry Immunization**
Policies must clearly define who will have access to registry information, and to which information they will have access. Policies must ensure that only authorized users may provide information to or receive information from the registry, and that there are procedures in place for handling requests from individuals and organizations that are not authorized users.
- **Penalties for Unauthorized Disclosures**
Policies must clearly define what constitutes a breach of confidentiality, and delineate the legal and administrative policies for the inappropriate use or disclosure of information. Penalties must be enforced.
- **Data Retention and Disposal**
Policies must address the period of time the information will be held in the registry and whether it will be deleted or archived at the end of that period. Registries must have a written policy that provides for the appropriate storage and disposal of all forms of confidential records.

The chapter includes a brief description of important privacy and confidentiality issues for registries that will need to be addressed in the future. These issues include, but are not limited to the following.

- **The interstate exchange of immunization information:** State laws differ and states with stringent legal protections may not allow disclosure to states with less protective laws.
- **Immunization registries that are part of larger, integrated information systems:** Are the minimum specifications adequate?
- **The relationship of managed care to immunization registries:** Issues such as who in the managed care organization should be authorized to access the registry and interstate data collection will need to be assessed.

- Removal of children's records from the registry: The issue of whether 18 year olds should be notified that they are in the registry or that their information will be archived needs to be explored, as well as the impact of state laws addressing the retention of medical records.

The chapter also contains 10 Key Action Steps to Ensure Privacy and Confidentiality and the appendix contains updated information on the security of health data.